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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,218	01/04/2002	Tom Mc Hale	12013/58801	3450

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,218

Applicant(s)

HALE ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14, 19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 14, 19, 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The indicated allowability of claims 6 is withdrawn in view of the new ground of rejection.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 4-7, 13, 14 are rejected under 35 U.S.C. 101 because the process does not produce a concrete and tangible result, there is no physical transformation appears in the claims. "Providing" is to make preparation, make available. "Providing" does not produce anything. "Selecting" is chosen from a number or group by fitness or preference. "Selecting" does not produce anything.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification discloses that chose the fold either by

inverse relationship between the inner coating hardness and the number of folds or but not and considering the number of cells in the coated medical implant.

6. Claims 1-11, 13, 14, 19, 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not define the hardness range of the coating and what number folds should be corresponded to that hardness range. One ordinary skill in the art would not know how many fold to select for certain stent have a certain hardness coating.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-11, 13, 14, 19, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "hardness" "the number of folds," "less folds," "more folds," "harder coatings" and "softer coatings" in claims is a relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of hardness is not defined in the specification and the number of fold corresponding to degree of hardness is not defined in the specification.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 4-7, 13, 14, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (6,153,252) in view of Fischell et al. (5,792,172). Hossainy et al. disclose a balloon-expandable stent including a plurality of cell (fig. 1-3), the stent being coated with a polymer layer containing therapeutic material (col. 3 to col. 6). Although, Hossainy et al. fails to disclose a balloon catheter having a multi-wing balloon for delivering the stent to a treated site, attention is directed to the Fischell et al. reference which teach a balloon with multifold for multi-wing for delivering a stent including a plurality of cells to a treated site, wherein the number of folds or wings of the balloon is the same as the number of the stent cells for improving the uniformity of stent cell expansion (col. 2, line 25 to col. 3, line 17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a catheter balloon as disclosed by Fischell et al. for delivering the stent of Hossainy et al. in order to improve the uniformity of stent cell expansion. Doing so would meet all the limitation of the claims.

Regarding to "the number of folds is selected using an inverse relationship between the inner coating hardness and the number of folds wherein less folds are selected for harder coatings and more folds are selected for softer coating." Since the

degrees of the hardness and the number of fold as claimed are not defined, Examiner has a position that the balloon of Hossainy et al. in view of Fischell et al. has an appropriate folds for the hardness of the coating of the stent of Hossainy et al. Therefore, the steps as claimed are inherently carried out by the teaching of Hossainy et al. in view of Fischell et al.

In regarding to claim 5, the number of folds provided in the multi-wing balloon inherently affects the coating on the coated medical implant. The limitation "related to the coating" is considered as the effect of the multi-wing on the coating.

In regarding to claim 22, since the balloon as disclosed by Fischell et al. having smooth external surface. There is no structure different between the claimed polished external surface and the smooth external surface of Fischell's balloon. NOTE: The introductory statement of intended use and all other functional statements such as "polished" have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the device of Hossainy et al. in view of Fischell et al.

11. Claims 3, 8, 9, 11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in view of Hillstead (5,116,318). Although, the teaching of Hossainy et al. in view of Fischell et al. fails to disclose a removable elastic membrane encircling the multi-wing balloon before crimping a coated stent onto the multi-wing balloon, attention is directed to the Hillstead reference which teaches an removable elastic membrane encircling the multi-wing balloon before crimping a coated stent onto the multi-wing balloon in order to

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provide protection to the balloon and to eliminate a blade-like or wing-like shape in a deflated configuration of the balloon so that to eliminate the possibility of trauma to a blood vessel (col. 2, lines 25-49; col. 3, line 48 col. 5, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an elastic membrane as disclosed by Hillstead into the balloon catheter of Fischell et al. for delivering the stent of Hossainy et al.. in order to provide a better delivery system which eliminates the possibility of trauma to a blood vessel being treated and doing so would meet the method steps of claims 8, 11 and 18-20, as placing the elastic membrane disclosed by Hillstead on the multi-wing balloon of Fischell et al., the surface of the multi-wing balloon would be smooth or polished as the elastic membrane eliminate "blade-like" or "wing-like" and the adhesion between the balloon and the coating would be prevented (the coated stent would only contact the membrane).

Regarding to "the number of folds is selected using an inverse relationship between the inner coating hardness and the number of folds wherein less folds are selected for harder coatings and more folds are selected for softer coating." Since the degrees of the hardness and the number of fold as claimed are not defined, Examiner has a position that the balloon of Fischell et al. in view of Hossainy et al. has an appropriate folds for the hardness of the coating of the stent of Hossainy et al. Therefore, the steps as claimed are inherently carried out by the teaching of Hossainy et al. in view of Fischell et al.

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12. Claims 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in view of Euteneuer et al. (5,147,302). Although, the teaching of Hossainy et al. and Fischell et al. do not explicitly disclose the multi-wing balloon being pre-treated such as heating the multi-wing balloon to reduce the multi-wing balloon surface profile, attention is directed to the Euteneuer et al. reference which teaches before placing a tubular sleeve on to a multi-wing balloon, reducing the profile of the multi-wing balloon by partially folding multi-wings of balloon around a core and heating the partially folded balloon to cause the wings to fold or wrap further around a core so that the balloon is more tightly wrapped than it was prior to the heat treatment in order to install the sleeve over the balloon more easily (col. 3, lines 53-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pre-treat the multi-wing balloon of Fischell et al. by heating the multi-wing balloon in order to reduce the profile of Fischell et al.'s balloon for facilitating ease of installation of Hossainy et al.'s stent. Doing so would reduce the adhesion between the balloon and the coated stent and the balloon with smaller profile would reduce the contact between the surface of the balloon and the inner surface of the stent as the stent installed over the balloon.

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in view of Hillstead '318 further in view of Trotta et al. (5,290,306) and Jung et al. (5,352,236). Although, the teaching of Hossainy et al. in view of Fischell et al. further in view of Hillstead fails to disclose an elastic membrane being pre-treated on outside and inside surfaces to

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reduce the adhesion between the coated stent and the membrane and between the membrane and the balloon, attention is directed the Trotta et al. and Jung et al. references which teach coating a lubricant on the inner or outer surface of an object in order to provide ease insertion. Jung et al. teach placing a lubricious material on an inner surface of a tubular sleeve in order to permits easy insertion of a wrapped balloon into the sleeve (col. 4, lines 36-44) and Trotta et al. teach placing a lubricant on the surface of a sleeve on a balloon in order to provide easy insertion of the balloon and the balloon may be carry an expandable stent (col. 2, lines 32-44 and col. 3, lines 6-13 and col. 4, lines 55-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a lubricious material on the inner and outer surface of the elastic membrane in order to provide easy insertion of the stent onto the sleeve or the balloon into the sleeve.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

March 8, 2006